UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **WAVE 6 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY IN SUPPORT OF MOTION TO EXCLUDE CERTAIN OPINIONS OF RALPH ZIPPER, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Defendants") submit this reply in support of their motion to exclude certain opinions of Ralph Zipper, M.D.

INTRODUCTION

Defendants have filed a motion seeking to exclude the following opinions proffered by Dr. Zipper regarding Defendants' TVT-S device:

- Alleged design defect opinions concerning mesh degradation, contraction, and extrusion that require biomaterials expertise that Dr. Zipper does not have;
- Alleged design defect opinions that are not supported by application of a reliable methodology;
- Alleged defective warnings contained in the TVT-S Instructions for Use ("IFU") that are outside of his expertise or that are not supported by a reliable methodology;
- "Safer" alternative products and procedures whose comparative safety and efficacy have not been quantified;
- Opinions about Ethicon's alleged knowledge, state of mind and bad acts;
- Opinions that amount to nothing more than historical commentary; and
- Opinions that have not been disclosed in his expert reports.

Plaintiffs have largely failed to respond to Defendants' arguments regarding alternative procedures, that the vast majority of his reports that are mere historical commentary, and opinions that have not been disclosed. By failing to respond to these arguments, Plaintiffs have conceded them, as this Court has repeatedly declined to make arguments for parties. *See, e.g.*, *Ramsey v. Bos. Sci. Corp.*, 2016 WL 2622006, at *4 (S.D. W.Va. May 5, 2016) ("The plaintiff does not address the majority of BSC's arguments on this point, and I decline to raise counterarguments for the plaintiff when she has failed to address BSC's arguments in her briefing.").

Additionally, Plaintiffs concede that they will not elicit any testimony from Dr. Zipper regarding Defendants' knowledge, state of mind, or alleged bad acts. (Resp. in Opp'n ("Resp.') at 16 (D.E. 5124)). Plaintiffs spend the majority of their response attempting futilely to convince the Court that Dr. Zipper's opinions are gained through experience and are based on sound methodology. They are not. Dr. Zipper's "experience" is, by his own admission, gained through litigation or is so nascent as to be inconsequential. He further fails to apply his purported methodology to all mesh products that he uses or opines on. For all of these reasons, and consistent with the foregoing, the Court should limit Dr. Zipper's testimony.

I. Dr. Zipper's Opinions That the TVT-S Was Defectively Designed Are Unreliable.

As demonstrated in Defendants' Motion, Dr. Zipper is not qualified to offer opinions regarding alleged design defects of TVT-S, nor are any of his opinions with respect to design defects reliable. (Mem. In Supp. of Mot. to Exclude ("Mem. In Supp.") at 3-11 (D.E. 5077)). In response, Plaintiffs rely on a Pennsylvania state court case in which Dr. Zipper was not excluded to argue that the result should be the same here. (Resp. at 4). Simply because a Pennsylvania state court has found Dr. Zipper qualified to testify in that jurisdiction does not mean that this

Court must accept his conclusory statements and his unreliable methodology. Plaintiffs contend that Dr. Zipper is qualified to opine regarding the biomaterial properties of mesh, including degradation, because he has "performed thousands of mesh and non-mesh incontinence and prolapse procedures" and "explanted hundreds of mesh devices." (Resp. at 5). This response essentially boils down to the contention that Dr. Zipper is an established urogynecologist with years of experience; therefore, the Court should find him qualified to testify as to biomaterial properties of mesh. This type of argument has failed to persuade this Court on previous occasions, *see, e.g.*, *Ramsey*, 2016 WL 2622006, at *5 ("The plaintiff fails to provide any argument addressing how Dr. Margolis is an expert on any of the above subject matters, beyond the basic assertion that Dr. Margolis is an established urogynecologist with years of experience with pelvic mesh products."), and it is no more persuasive now.

Plaintiffs additionally contend that Dr. Zipper has "worked closely with engineers to develop devices and mesh products for the treatment of urinary incontinence and pelvic organ prolapse," (Resp. at 7), but offers no evidence that Dr. Zipper himself designs the products. He merely "craft[s] instructional materials and marketing materials." (*Id.*). Not only does Dr. Zipper's work with engineers fail to qualify *him* to offer opinions based on those engineers' knowledge, skill, experience, or training (*see* Mem. In Supp. at 5), this Court has previously precluded a urogynecologist from testifying about product design where the urogynecologist lacked experience with the actual design of the product. *See Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 581 (S.D. W. Va. 2014). It should do the same in this case.

More importantly, Plaintiffs wholly fail to address Defendants' contention that Dr. Zipper's methodology is unreliable. (*See* Mem. In Supp. at 7-8). Although Dr. Zipper has vigorously campaigned against Defendants' polypropylene mesh products by criticizing their

safety, when confronted with questions regarding his application of these criteria to a polypropylene mesh he uses today, called Alyte Y, Dr. Zipper admitted that he does not apply these criteria to Alyte Y. (*Id.*). Plaintiffs do not even bother trying to explain this discrepancy. Dr. Zipper also offers and implants his patients with polypropylene mesh retropubic mid-urethral slings. Contrary to Plaintiffs' representation, Dr. Zipper does not "painstakingly differentiate between" the slings that he offers from the TVT-S sling, aside from specifying that the slings he offers are made by American Medical Systems and Boston Scientific. (Resp. at 9). Plaintiffs offer no evidence that the slings Dr. Zipper implants are of a different mesh than the TVT-S. Plaintiffs claim that Dr. Zipper "detailed additional critical design differences of the TVT-S from full-length mid-urethral slings," specifically, the TVT-S fixation tips, but that does not change the fact that Dr. Zipper believes *all* mesh to be unsafe. (Resp. at 9). Yet he implants it anyway.

His opinion does not "comport[s] with the dictates of good science" as required by *Daubert*, *see Sanchez v. Boston Sci. Corp*., No. 2:12-CV-05762, 2014 WL 4851989, at *4 (S.D. W. Va. Sept. 29, 2014) *reconsideration denied*, No. 2:12-CV-05762, 2014 WL 5320559 (S.D. W. Va. Oct. 17, 2014), and is not the product of reliable principles and methods applied to the facts of this case. Dr. Zipper's opinions regarding design defect should be excluded. *See Stewart v. Bos. Sci. Corp.*, 2016 WL 2654080, at *11 (S.D. W. Va. May 9, 2016) (excluding Dr. Blaivas's opinion because he applied standards different than those he applies in his medical practice).

II. Dr. Zipper's Has Not Offered a Sufficient Basis for His Opinions That There Were Safer Alternative Products or Procedures.

Dr. Zipper opines that there were a number of other alternative products or techniques that were equally effective to treat stress urinary incontinence than the TVT-S, such as native tissue procedures and a variety of other mesh products. (Mem. In Supp. at 11-14). Defendants

have moved to exclude these opinions on two grounds. First, alternative *products* and *procedures* are not alternative *designs*, and do not satisfy the Plaintiffs' burden of establishing a safer alternative *design*. Plaintiffs have evaded the question, terming full-length mid-urethral slings, non-mesh procedures, and suture procedures simply "safer alternatives," ignoring the facts that they must show a safer alternative *design*, and that these are all other products or other procedures. (Resp. at 10-11). These opinions should be excluded.

Second, for Dr. Zipper to opine that traditional surgical procedures are safer alternatives to Ethicon's products presumes that all mesh products are unsafe. (Mem. In Supp. at 12). Such an "argument . . . really takes issue with the choice of treatment made by [the patient]'s physician, not with a specific fault of" the device. *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th. Cir. 1999) (surgical alternative to pedicle screw could not be considered). Plaintiffs' response obliquely addresses "alternative designs using larger pore, lighter weight mesh (e.g., Ultrapro)," but given Dr. Zipper's underlying opinions that traditional, non-mesh procedures are all safer than mesh itself, and that even a TVT-S made with Ultrapro would be defective, he cannot reliably opine that "larger pore, lighter weight mesh (e.g., Ultrapro)" is a safer alternative design. (Resp. at 11).

Furthermore, Defendants argued that Dr. Zipper had failed to disclose testing that supported his opinion and failed to link his conclusions to the analysis that he performed with respect to any such testing. (Mem. In Supp. at 12-13). In their Response, Plaintiffs still provide no evidence that Dr. Zipper tested this theory, citing only to "medical literature and internal company documents." (Resp. at 13). This is clearly insufficient to demonstrate the reliability of Dr. Zipper's opinions. *See, e.g., Johnson v. Manitowoc Boom Trucks, Inc.*, 406 F. Supp. 2d 852, 860-62 (M.D. Tenn. 2005) (stating that "testing is important, especially in the context of a theory

involving a proposed alternative design"); *see also Bourelle v. Crown Equip. Corp.*, 220 F.3d 532, 538 (7th Cir. 2000) (holding the lower court did not err in excluding expert testimony in large part because the expert had not tested his alternative design). His opinions regarding safer alternative design should be excluded.

III. Dr. Zipper Admittedly Became an Expert in Warnings Through Litigation, and He is Not Qualified to Offer Opinions Regarding The Adequacy Of The TVT-S IFU.

Ethicon has moved to dismiss Dr. Zipper's opinions the IFU that accompanied the TVT-S were defective and failed to provide adequate warnings and information to treating surgeons. (Mem. In Supp. at 14-17). In particular, Dr. Zipper has insufficient experience in preparing a medical device IFU and no training concerning FDA regulations related to developing warnings or labeling. (*Id.* at 14). More critically, however, Dr. Zipper has essentially testified that he has become an expert in labeling and the FDA regulatory process through litigation. (*Id.* at 15). Plaintiffs fail to respond to this argument in their Response. (Resp. at 14-16). Instead, Plaintiffs claim that Dr. Zipper has "recently acquired . . . experience in drafting IFU's [sic] for medical devices." (Resp. at 14). An examination of Dr. Zipper's testimony demonstrates that this is not entirely the case. As Ethicon pointed out in its Motion, Dr. Zipper is currently "in the process" of drafting IFUs for device unrelated to the TVT-S or the condition it treats. (Mem. In Supp. at 15-16). The products do not even have a completed warning label; Dr. Zipper has scarcely completed the process. Tackling the initial stages of label drafting should not serve to make one an "expert" in labeling standards in federal court. He lacks familiarity with the *process* of developing product warnings, as was required by this Court in *Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013) (excluding plaintiff's expert, Dr. Bob Shull, on warnings and labels for medical devices: "Despite his stellar qualifications as a urogynecologist, Dr. Shull is unqualified to testify on the specific issue of product warnings, as evidenced by his lack of

familiarity with the process"). Plaintiffs further fail to respond to Ethicon's argument that Dr. Zipper has failed to explain why the TVT-S IFU should have warned of complications that were commonly known in the medical community. Dr. Zipper's opinions regarding warnings should be excluded.

CONCLUSION

For the reasons set forth above, the Court should limit the parameters of Dr. Zipper's testimony consistent with the foregoing.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this date I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

*/s/ Christy D. Jones*_____
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